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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,395	12/27/2000	Thomas Specht	SCH-1780	6808

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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/20/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,395	SPECHT ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,26,28,29 and 33-40* is/are pending in the application.

4a) Of the above claim(s) *1-22,28,29 and 33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,26,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed October 21, 2002. Currently, claims 23-24, 26, 39-40 are under consideration. Claims 1-22, 28, 29, 33-38 are withdrawn from consideration as drawn to non-elected subject matter.

2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.

3. Any objections and rejections not reiterated below are hereby withdrawn in view of applicants arguments and the amendments to the claims.

Maintained Rejections

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-24, 26, and Newly added Claims 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using polypeptides of SEQ ID NO: 238, does not reasonably provide enablement for polypeptides which are 80%, 90% identical with SEQ ID NO: 238. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches numerous genes and their expression patterns in different tissues as compared to cancerous tissues. The gene product of SEQ ID NO:

33, which encodes the polypeptide of SEQ ID NO: 238 is expressed 39 times more frequently in cancerous tissue as compared to normal uterus-endometrial tissue.

The art does not teach how to use polypeptides which are 80%, 90% identical with sequences of SEQ ID NO: 238.

Neither the specification nor the art teach the skilled artisan how to use the invention as broadly as claimed. The specification nor the art teaches the skilled artisan how to use the polypeptides which are 80% or 90% identical with SEQ ID NO: 238. While the specification teaches that SEQ ID NO: 238 is overexpressed in uterus-endometrium cancer tissue as compared with normal tissue, the specification does not teach how to use sequences which are similar to SEQ ID NO: 238. The skilled artisan would be required to perform undue experimentation on the variant SEQ ID NO: 238 to determine whether the variant sequences are also overexpressed in the cancerous tissue or whether the sequences are found only in normal tissue. Similarly, the specification does not teach how to use partial sequences from SEQ ID NO: 238 because it is unclear whether these partial sequences are specific to the polypeptide.

Response to Arguments

The response traverses the rejection. The response asserts that it is well known in the art what is meant by homology and that it is known in the art how to test for overexpression of a peptide such that no undue burden would be required to practice the claimed invention (response filed October 21, 2002, page 3). This argument has been reviewed but is not convincing because while one could conduct additional experimentation to determine whether, e.g. expression of SEQ ID NO: 238 at certain

levels might be associated with, e.g., endometrial cancer tissue, the outcome of such research cannot be predicted, and such further research and experimentation are both unpredictable and undue. The teachings in the specification do not establish that one could actually detect expression of polypeptides at least 80% identical with SEQ ID NO: 238 or comprising SEQ ID NO: 238 as an indicator of endometrial cancer tissue. Rather the teachings of the specification illustrate that SEQ ID NO: 33 is expressed at higher levels in endometrial cancer tissue. It is unpredictable whether any quantity of experimentation would allow one to practice the claimed invention. Accordingly, it would requires undue experimentation for a skilled artisan to use the claimed invention. Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 23-24, 26 and Newly amended Claim 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptide which are 80% or 90% identical with polypeptide of SEQ ID NO: 238 or comprise SEQ ID NO: 238.

The specification teaches SEQ ID NO: 238 is expressed 39 times more frequently in cancerous uterus-endometrium tissue as compared to normal tissue. SEQ ID NO: 238 is 108 amino acids in length.

The specification does not appear to teach a full protein, therefore, claims to a polypeptide comprising the partial polypeptide sequence reads upon a full protein which has not been described. The partial polypeptide sequence does not begin with a start codon, therefore, the partial polypeptide sequence does not appear to be a full protein.

Response to Arguments

The response traverses the rejection. The response asserts that the claims have been amended to render the rejection moot. This argument has been reviewed but is not convincing because the claims have been amended to recite "comprising SEQ ID NO: 238", 80% and 90% identical to SEQ ID NO: 238 and consisting essentially of SEQ ID NO: 238. First, consisting essentially of is interpreted broadly to encompass claim language of comprising.

The specification teaches that SEQ ID NO: 33 is a partial cDNA produced from individual ESTs by assembling and editing. SEQ ID NO: 238 the polypeptide which is encoded by the partial SEQ ID NO: 33. Therefore, SEQ ID NO: 238 is not a full protein. The claims read upon a full protein which has neither been provided nor described. Similarly, the percent homolog polypeptides have not been described because the specification fails to describe any variants of SEQ ID NO: 238 which maintain the same function as SEQ ID NO: 238. Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claim 24 is rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (US Pat. 6,174,992, January 2001).

Ni et al. (herein referred to as Ni) teaches a hESF III polypeptide sequence, namely SEQ ID NO: 6, which is 100% identical to amino acid positions 14-108 of the instant application's SEQ ID NO: 238. The polypeptide is 87.9% identical with SEQ ID NO: 238. Therefore, hESF III, SEQ ID NO: 6 of Ni is a polypeptide partial sequence of SEQ ID NO 238.

Response to Arguments

The response traverses the rejection. The response asserts that the claims have been amended to overcome the rejection. The response asserts that claim 23 has been amended to require the entire sequence. This argument has been reviewed but is not

convincing because Claims 24 and 40 are directed to sequences which are 80% identical with SEQ ID NO: 238. Ni teaches a sequence which is 87.9% identical with SEQ ID NO: 238, therefore, the reference still anticipates the claimed invention. Thus for the reasons above and those already of record, the rejection is maintained.

7. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Ni et al. (WO 97/34997, September 1997).

Ni et al. (herein referred to as Ni) teaches a hESF III polypeptide sequence, namely SEQ ID NO: 6, which is 100% identical to amino acid positions 14-108 of the instant application's SEQ ID NO: 238. The polypeptide is 87.9% identical with SEQ ID NO: 238. Therefore, hESF III, SEQ ID NO: 6 of Ni is a polypeptide partial sequence of SEQ ID NO: 238.

Response to Arguments

The response traverses the rejection. The response asserts that the claims have been amended to overcome the rejection. The response asserts that claim 23 has been amended to require the entire sequence. This argument has been reviewed but is not convincing because Claims 24 and 40 are directed to sequences which are 80% identical with SEQ ID NO: 238. Ni teaches a sequence which is 87.9% identical with SEQ ID NO: 238, therefore, the reference still anticipates the claimed invention. Thus for the reasons above and those already of record, the rejection is maintained.

Allowable Subject Matter

8. Claim 39 is drawn narrowly to a polypeptide consisting of SEQ ID NO: 238. SEQ ID NO: 238 is free of the art. The specification, page 170, teaches that the polypeptide encodes SEQ ID NO: 33, in part. SEQ ID NO: 33 is an mRNA which is expressed 39 times 39 times more frequently in cancerous uterus-endometrium tissue as compared to normal tissue. Therefore, the polypeptide of SE QID NO: 238 is allowable.

Conclusion

9. Claim 39 is allowable. Claims 23-24, 26, 40 are not allowable.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg
December 12, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600